4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA-2017-N-6216]

General Hospital and Personal Use Devices; Reclassification of Sharps Needle Destruction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify the needle destruction device, renaming the device to "sharps needle destruction device," a postamendments class III device (regulated under product code MTV), into class II (special controls), subject to premarket notification. FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on new information. The Agency is classifying the device into class II (special controls) to provide a reasonable assurance of safety and effectiveness of the device. This order reclassifies these types of devices from class III to class II and will reduce regulatory burdens on industry because these types of devices will no longer be required to submit a premarket approval application (PMA), but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3). Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device

into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 388-391 (D.D.C. 1991)) or in light of changes in "medical science" (*Upjohn* v. *Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the "new information" to support reclassification under 513(f)(3) must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

On November 7, 2017, FDA published an order in the *Federal Register* to reclassify the device (82 FR 51585) (the "proposed order"). The period for public comment on the proposed order closed on January 8, 2018. FDA received and has considered two comments on the proposed order, as discussed in section II.

II. Comments on the Proposed Order and FDA Response

A. Introduction

We received two comments on the proposed order and both comments supported the proposed reclassification. The comments were received from a consumer and a healthcare professional in the drug industry.

We describe and respond to the comments in section B of this section. The order of response to the commenters is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received.

B. Description of Comments and FDA Response

(Comment 1) One commenter discussed the experience of witnessing sharps disposal and was supportive of safe and cost-effective options for sharps disposal due to the potential injury to sanitation works or patients/users with improper disposal of sharps. The commenter was generally supportive of FDA's proposed reclassification. Additionally, the commenter stated that PMA requirements increase the price of these devices and that reclassification increases affordability of the sharps needle destruction devices, while ensuring safety.

(Response 1) FDA agrees with this comment. The Agency believes that reclassification of the sharps needle destruction device will reduce the regulatory burden on manufacturers, which could increase patient access to these devices and potentially reduce accidental needle sticks, while still providing reasonable assurance of safety and effectiveness. Additionally, FDA believes the special controls mitigate workplace hazards associated with sharps needle destruction and ensures proper use of the device.

(Comment 2) One commenter noted that while a PMA for these devices will no longer be required, FDA will still require premarket notification under section 510(k) of the FD&C Act. The commenter stated that in addition to 510(k) requirements, a prescription use restriction, and labeling, the identified special controls will provide reasonable assurance of device safety and effectiveness. The commenter noted that PMAs delay the access of these devices to patients. The commenter concluded that this reclassification may factor in positive outcomes for patient access and safety.

(Response 2) FDA agrees with this comment. The Agency believes that the special controls required in this final order provide a reasonable assurance of safety and effectiveness for these devices. FDA believes it has identified the risks to health (see section V of the proposed order) and that the measures described in this final order will be effective in mitigating the identified probable risks to health. Additionally, by reclassifying these types of devices from class III to class II, this will reduce regulatory burdens on industry because these types of devices will no longer be required to submit a PMA, but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

III. The Final Order

FDA is adopting its findings under section 513(f)(3) of the FD&C Act, as published in the preamble to the proposed order. FDA is issuing this final order to reclassify needle destruction devices from class III to class II, rename them sharps needle destruction devices, and establish special controls by revising 21 CFR part 880. In this final order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, provide a reasonable assurance of the safety and effectiveness for sharps needle destruction devices.

FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act under section 510(m) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of sharps needle destruction devices, and therefore, this device type is not exempt from premarket notification requirements.

The device is assigned the generic name sharps needle destruction device, and it is identified as a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

Under this final order, the sharps needle destruction device is a prescription use device under § 801.109 (21 CFR 801.109). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) requirements.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E have been approved under OMB control number 0910-0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*, as amended) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

2. Add § 880.6210 to subpart G to read as follows:

§ 880.6210 Sharps needle destruction device.

(a) *Identification*. A sharps needle destruction device is a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) Performance testing must demonstrate the following during operation of the device:

(i) The device safely contains or ventilates aerosols or fumes from device operation.

(ii) Excessive heat or sparks are not generated that may injure users or patients.

(iii) Simulated use testing must demonstrate sharps and/or needles are completely destroyed using a range of types and sizes of sharps sufficient to represent actual use.

(iv) Simulated use testing must demonstrate that the device is physically stable on the surface for which it is intended to be mounted to ensure the risk of harm to the patient/user as a result of the device falling is minimized.

(2) Validation of cleaning and disinfection instructions must demonstrate that the device can be safely and effectively reprocessed after use per the recommended cleaning and disinfection protocol in the instructions for use.

(3) Analysis and/or testing must validate electromagnetic compatibility and electrical safety, including the safety of any battery used in the device, under conditions which are consistent with the intended environment of device use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Labeling must include:

(i) A clear description of the device and its technological features;

(ii) How the device is to be used, including validated cleaning and disinfection instructions;

(iii) Relevant precautions and warnings based on performance and in-use testing to ensure proper use of the device; and

(iv) Instructions to install device in adequately ventilated area and stable area.

Dated: April 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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